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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: BEXTRA MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	Case No. M:05-CV-01699-CRB MDL No. 1699
THIS PLEADING RELATES TO: *ASEA/AFSCME Local 52 Health Benefits Trust v. Pfizer, Inc., et al.*, Case No.: 1:05-cv-03803-LTS (S.D.N.Y.) *Clara Fontanilles v. Pfizer, Inc.*, Case No.: 05-21241-CIV-Martinez/Banstra (S.D. Fla.) *Linda A. Watters, et al. v. Pfizer, Inc., et al.*, Case No.: 2:05cv71434 (E.D. Mich.) *Ronnie L. Hatcher v. Pfizer, Inc., et al.*, Case No. 1:05-cv-00208-SLR (D. Del.) *Steamfitters' Indus. Welfare Fund, et al. v. Pfizer, Inc., et al.*, Case No.: 05 cv 3814 (S.D.N.Y.) *Nancy Ayers, et al. v. Pfizer, Inc., et al.*, Case No. 05-CV-03770 (N.D. Cal.) *Betty A. Alexander, et al. v. Pfizer, Inc., et al.*, Case No.: 05-cv-01720-ML-ALC *National Health Ins. Co. v. Pfizer, Inc., et al.*, Case No.: 05-cv-04073 (N.D. Cal.) *Nancy Milano v. Pfizer, Inc.*, Case No.: C-05-3710 MHP (N.D. Cal.)	**THIRD AMENDED PURCHASE CLAIMS MASTER BEXTRA COMPLAINT**

TABLE OF CONTENTS

PAGE

I. NATURE OF THIS ACTION

A. Procedural Introduction

1. This Master Complaint is submitted to serve the administrative functions of efficiency and economy through presenting certain common claims and common questions of fact and law for appropriate action by this court in the context of this Multidistrict proceeding. This Master Complaint does not include all claims asserted in all of the purchase claims actions that have been transferred to this Court under 28 U.S.C. § 1407. Those matters are set forth in the individual and class actions filed by purchased claims Plaintiffs and served against Defendants. This Master Complaint does not constitute a waiver or dismissal of said actions or the claims asserted therein.

2. This Class Action is brought by and on behalf of all Consumers and Third-Party Payors (Consumers and Third-Party Payors are referred to herein collectively as "Plaintiffs," "Class Members," and "End-Payors") who purchased or paid for the prescription drug Bextra ("Bextra"), an anti-inflammatory drug researched, manufactured, marketed, promoted, advertised, sold, and distributed by a combination and/or collaboration of Defendants Pfizer, Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle & Co. ("Searle").

3. Pursuant to Rule 23(b)(1), 23(b)(2), 23(b)(3), and/or 23(c)(4)(A) of the Federal Rules of Civil Procedure, Plaintiffs will seek certification of a national End-Payor purchase claims class, through one or more actions transferred to or filed in this Court in the MDL 1699 litigation, consisting of:

> All End-Payors located in the United States, including Consumers and Third Party Payors,[1] who purchased and/or paid for Bextra.[2]

4. Alternatively, in the event that this Court determines that a national End-Payor purchase claims class would not satisfy the requirements for class certification pursuant to Fed. R. Civ. P. 23, Plaintiffs would move for the certification of individual state class actions, grouped

[1] Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

[2] The class is further defined in Section VI, *infra*.

according to commonalities of state law consisting of, as to each state for which certification is sought:

> All End-Payors located in [State], including consumers and Third Party Payors, who purchased and/or paid for Bextra.[3]

5. In the event that Plaintiffs are directed to pursue the statewide class course of action set forth in the forgoing paragraph, Plaintiffs intend to request the Panel for Multi-District Litigation ("MDL Panel" or "Panel") to remand, to its transferor forum, each state class action as to which Plaintiffs seek certification, solely for purposes of addressing the class certification question. Remand of the class certification question will allow appellate review of the statewide class certification question by the appropriate Circuit Court(s), thus ensuring that no party will have been prejudiced by the Panel's random selection of a transferee forum whose procedural jurisprudence would determine the class certification issue differently from that of the transferor forum that is charged with its ultimate trial. For purposes of uniformity and judicial efficiency, Plaintiffs would further move the MDL Panel to appoint this Court to sit, by *ad hoc* designation, over the class certification issue in each transferor court as to which such remand is sought.

B. Summary of Allegations

6. Non-steroidal anti-inflammatory drugs ("NSAIDs") have been widely used to treat arthritis, acute and chronic pain for nearly 40 years. The pain relief offered by such NSAIDs comes at the expense of important adverse effects, most notably upper gastrointestinal toxicity. Use of NSAIDs leads to admission to hospital for ulcer complications (bleeding and perforation) in around 1% of users annually and results in thousands of deaths every year.

7. In 1989, scientists made a breakthrough in understanding how NSAIDs worked. Cyclo-oxygenase, the enzyme inhibited by NSAIDs, exists in at least two forms in the body. Traditional NSAIDS inhibit both the cyclo-oxygenase 2 ("COX-2") enzyme, which is inducible and expressed at sites of inflammation, and the COX-1 enzyme, which is constitutive and expressed in the gastrointestinal ("GI") system. Inhibition of the COX-2 enzyme decreases inflammation and alleviates pain. Inhibition of the COX-1 enzyme, however, decreases the

[3] This Class is further defined in Section VI and in the specific claims for relief.

protection in the GI tract. Defendants leapt at this new understanding, hoping to create a new breed of NSAID that alleviated pain, but did not have the GI toxicity associated with traditional NSAIDs.

8. Bextra was one of the new COX-2 inhibitors, Vioxx and Celebrex are others. Defendants believed that Bextra had the potential to be a new blockbuster drug with yearly sales in the billions of dollars.

9. As part of the unlawful scheme set forth below, Defendants promoted the use of Bextra in information disseminated to doctors, Pharmacy Benefit Managers ("PBMs"), third-party payors and consumers. Defendants promoted Bextra as a "breakthrough" drug providing important clinical advantages over older and far less expensive NSAIDs. Defendants were never able to establish, however, that Bextra was any more efficacious or safer than traditional NSAIDs. To the contrary, studies showed risks for gastrointestinal and cardiovascular ("CV") adverse event rates similar to or greater than traditional NSAIDs. The FDA approved label warned of GI and CV risks similar to other NSAIDs. Even so, as part of the unlawful scheme set forth below, Defendants embarked on a massive marketing campaign directed to doctors, third party payors and consumers to market Bextra as a "Powerful" drug clinically superior to and safer than older and far less expensive NSAIDs.

10. Defendants falsely represented that Bextra provided symptomatic relief similar to ibuprofen and naproxen but was clinically superior because it was significantly less likely to cause the gastrointestinal adverse side effects associated with these and other NSAIDs. For instance, NSAIDs can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Defendants falsely promoted Bextra as a safe and effective alternative that would have less deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

11. The extent to which a drug is paid for by third-party payors is determined by that drug's status on the third-party payor's "formulary," which is a list of drugs that plan participants are authorized to purchase for payment under the benefit plan.

12. Placement of a prescription drug on the formularies of third-party payors, medical care organizations, and or prescription benefit managers (who are employed by the third-party payors to design or administer the benefit plans) is critical to the success of the drug. Defendants knew that preferred placement on these formularies would guarantee commercial success for Bextra.

13. In an elaborate and sophisticated manner, Defendants aggressively marketed Bextra directly to medical professionals (including physicians, dentists, and leading medical scholars) in order to leverage pressure on third-party payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include Bextra on their formularies. Bextra's marketing campaign specifically targeted third-party payors, physicians and dentists, and was designed to convince them of both the therapeutic and economic value of Bextra. Faced with the increased demand for the drug by health care professionals that resulted from Bextra's successful advertising and marketing blitz, third-party payors were compelled to add Bextra to their formularies.

14. Defendants' marketing and promotion of Bextra was part of a scheme to create the impression of, and demand for, Bextra as a wide-ranging pain reliever, particularly for the treatment of arthritis pain and/or pain in general (a use for which it was not FDA approved). The scheme was accomplished by unlawful means including, but not limited to, the (i) false promotion, including promotion contrary to the FDA approved label, of the overall efficacy and safety of Bextra as superior to less expensive alternatives, (ii) false promotion, including promotion contrary to the FDA approved label of the CV and GI safety of Bextra, (iii) manipulation of data to give the appearance of superiority over other NSAIDs in pain relief efficacy, CV and GI safety when such superiority did not exist and was contrary to the FDA approved label, (iv) false promotions, including promotions contrary to the FDA approved label, directed to doctors, third party payors and consumers, touting the superior efficacy and GI and CV safety of Bextra, which promotions exceeded the scope of FDA approval, (v) use of reprinted articles from prestigious medical journals that falsely claimed Bextra was proven to be safer than other NSAIDs contrary to the FDA approved label and (vi) co-promotion of Bextra with Celebrex in an attempt to convince doctors

incorrectly that the alleged benefits of one drug applied to both even though such claims were contrary to the FDA approved label of each drug.

15. As a result of Defendants' scheme, they were able to create a market for Bextra and to sell Bextra at a premium price over NSAIDs and to have it become a standard treatment option in many circumstances as opposed to use of less expensive NSAIDs. Bextra sales reached $1.29 billion in 2004.

16. The success of Defendants' scheme was recently documented in a study released on January 24, 2005, in the ARCHIVES OF INTERNAL MEDICINE, Volume 165, entitled *National Trends in Cyclooxygenase-2 Inhibitor Use Since Market Release*. The authors of that study concluded that the "aggressive marketing techniques to patients and physicians" caused a growth not only in use of COX-2 inhibitors but also in overall market demand, resulting in the use of such drugs for patients who did not need them.

17. In fact, Bextra has been promoted as a superior pain reliever when for most patients it has no proven superiority over other NSAIDs. To date there are ***no*** clinical studies that demonstrate an advantage of Bextra over other NSAIDs that would offset concerns about serious skin risks (*e.g.*, toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme), such as studies showing a GI safety benefit compared to other products. In addition, Bextra has been documented to be associated with increased risk of serious adverse cardiovascular events to such an extent, that on April 7, 2005, the Federal Drug Administration ("FDA") requested Pfizer to withdraw Bextra from the United States market and Pfizer has done so. At the FDA briefing called to explain its request that Pfizer withdraw Bextra from the market, the FDA's director of the Office of New Drugs said that Bextra "had no unique benefit and it had the unique risk: the skin reaction."[4]

18. Bextra sold during the Class Period for $2.53 to $6.45 per day depending upon the dose, while NSAIDs sold for as little as $0.21 to $0.31 per day. Billions of dollars have thus been wasted in which Plaintiffs and Class Members have paid a premium price for a drug (and the doctor visits necessary to obtain prescriptions for Bextra) that is not a premium or superior product

[4] Rita Rubin, "Another drug for pain off market," *USA Today*, 4/7/2005.

over equally available, less expensive NSAIDs and other pain medications. If Defendants had not engaged in the wrongful marketing, advertising and promotion of Bextra, Plaintiffs and Class Members would have paid for other, equally effective and less expensive medications or would have purchased no medication at all. Had the truth been told about its safety and efficacy, Bextra would have sold at a price similar to that of other NSAIDs and would not have become a standard in the treatment of arthritis, dysmenorrheal and other non-FDA approved forms of pain relief, and/or Bextra would not have been marketed at all and would not have been approved on formularies. The plain fact is that at no time did Bextra, as compared to other, equally effective and less expensive therapeutic regimens, have a proven advantage for patients either at no risk or at high-risk for GI complications. Thus, for virtually every purchaser – and contrary to Defendants' widespread marketing program – Bextra was neither more effective nor safer than older, less expensive NSAIDs and thus was not a superior product.

19. In this action Plaintiffs seek damages arising from the purchases of Bextra resulting from Defendants' illegal scheme and/or conduct.

II. JURISDICTION

20. This Court has subject-matter jurisdiction under the Class Action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a new subsection (d) and confers federal jurisdiction over class actions where, as here, "any member of a class of Plaintiffs is a citizen of a State different from any defendant" and the aggregated amount in controversy exceeds five million dollars ($5,000,000). *See* 28 U.S.C.§§ 1332(d)(2) and (6).

21. This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and because Defendants systematically and continually conduct business throughout the State of California, including marketing, advertising, and sales directed to California residents.

22. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, and Defendants may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through providers and sales

representatives who reside or transact business in this District, and thereby affected Class Members who similarly reside or transact business in this District.

III. PARTIES

A. Plaintiffs

23. Plaintiff Betty A. Alexander, who filed Civil Action No. 05-1720 (E.D. La.), is a person of the full age of majority domiciled in Orleans Parish, Louisiana, and is a Louisiana consumer who paid for the prescription drugs Bextra and Celebrex.

24. Plaintiff Allied Services Division Welfare Fund ("ASD"), who filed Civil Action No. 05-1720 (E.D. La.), is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. ASD is a multi-employer employee welfare benefit plan within the meaning of the Employee Retirement Income Security Act, 29 U.S.C. § 1001(2), and § 1002(37). ASD paid for prescriptions of Bextra and Celebrex dispensed to covered lives in several states. ASD has paid and provided, and will in the future pay and provide, health care benefits to its members and insureds as a direct result of the wrongful conduct of the Defendants as fully alleged herein.

25. Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust ("ASEA"), who filed Civil Action No. 1:05-cv-03803-LTS (S.D.N.Y.), is a self-funded health benefit trust that was created through collective bargaining between the State of Alaska and ASEA/AFSMCE Local 52 to provide reimbursement for eligible health, vision, dental and prescription drug claims incurred by employees of the State of Alaska who are members of the General Governmental Unit represented by ASEA/AFSCME Local 52. ASEA's Anchorage headquarters are located at 1577 C Street, Suite 201, Anchorage, Alaska 99501. ASEA paid some or the entire purchase price for Bextra during the relevant period and was injured by the illegal conduct alleged herein.

26. Plaintiff Clara Fontanilles ("Fontanilles"), who filed Civil Action No. 05-21241-CIV-Martinez/Banstra (S.D. Fla.), is a resident of Miami-Dade County, Florida, and is otherwise *sui juris*. During the proposed Class Period, Fontanilles was prescribed, purchased

and consumed Bextra within the state of Florida, and is a member of the proposed Class as defined below.

27. Plaintiff Frankenmuth Financial Group, Inc. ("Frankenmuth"), who filed Civil Action No. 2:05cv71434 (E.D. Mich.), is a Michigan corporation headquartered in Saginaw County, Michigan. At all times relevant to this Complaint, Frankenmuth was a third-party payor whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. During times relevant to this lawsuit, Frankenmuth paid for prescriptions for Bextra and was injured by the illegal conduct alleged herein.

28. Plaintiff Ronnie L. Hatcher ("Hatcher"), who filed Civil Action No. 1:05-cv-00208-SLR (D. Del.), resides in Elizabethtown, Kentucky. During the Class Period, Mr. Hatcher was prescribed and paid for part of the purchase price of the Bextra and was injured by the illegal conduct alleged herein.

29. Plaintiff Nancy Milano ("Milano"), who filed Civil Action No. C-05-3710 MHP (N.D. Cal.), is a resident of San Mateo County, California. During the Class Period, Ms. Milano was prescribed and paid for part of the purchase price of Bextra and was injured by the illegal conduct alleged herein.

30. Plaintiff Metal Trades Branch Welfare Fund ("Metal Trades"), who filed Civil Action No. 05 cv 3814 (S.D.N.Y.), is a union health and welfare fund that provides health and prescription drug benefits to its members, and specifically, it has paid or reimbursed members for prescription drug benefits for Bextra and was injured by the illegal conduct alleged herein. Metal Trades is headquartered in the city of New York, in the State of New York.

31. Plaintiff National Healthcare Insurance Company ("NHCI"), who filed Civil Action C05-04073 (N.D. Cal.), is a life and health insurance company with its principal place of business at 1901 North State Highway 360, Grand Prairie, Texas 75050, and is involved in the business of providing health benefits, among others, to covered lives. NHCI paid for prescriptions of Bextra and Celebrex dispensed to covered lives in several states. NHCI has paid and provided, and will in the future pay and provide, health care benefits to its members and insureds as a direct result of the wrongful conduct of Defendants as fully alleged herein.

32. Plaintiff Vernon Shepherd ("Shepherd"), who filed Civil Action No. 05 CH 9482, is an adult resident of Mundelein, Illinois in Lake County. Mr. Shepherd first began taking Bextra in early 2005 when Bextra was prescribed for him by his doctor and he purchased the drug. Mr. Shepherd was continually prescribed, purchased and used Bextra from early 2005 until April 2005 when the product had been removed from the market. At that time, he heeded Pfizer's instructions to consult his doctor for alternative treatment. He made an appointment and visited his doctor. He was thereafter charged with the cost of this doctor visit.

33. Plaintiff Steamfitters' Industry Welfare Fund ("Steamfitters"), who filed Civil Action No. 05 cv 3814 (S.D.N.Y.), is a union health and welfare fund that provides health and prescription drug benefits to its members, and specifically, it has paid or reimbursed members for prescription drug benefits for Bextra for its members and was injured by the illegal conduct alleged herein. Steamfitters is headquartered in the city of New York, in the State of New York.

34. Plaintiff Linda A. Watters, Commissioner, Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc., who filed Civil Action 2:05cv71434 9 (E.D. Mich.), is a Michigan official whose function is to collect and liquidate all assets and liabilities of the former private third-party payors' Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness Plan and OmniCare were private third-party payors whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. During times relevant to this lawsuit, Wellness Plan and OmniCare paid for prescriptions of Bextra and was injured by the illegal conduct alleged herein.

35. Plaintiff Nancy Ayers ("Ayers"), who filed Civil Action No. 05-CV-03770, was at all relevant times, an adult resident citizen of the State of California, and resident of Bakersfield, Kern County.

36. Plaintiff Nancy Ayers was prescribed, and began taking, Bextra on or about October 12, 2004. She paid for two prescriptions of Bextra, which each cost her $21.52 in out-of-

pocket expenses for a total expenditure of $43.04. She had switched to Bextra after Vioxx was recalled.

37. As a direct and proximate result of using Bextra, Plaintiff Nancy Ayers suffered severe cardiovascular and cerebrovascular injuries. Specifically, on December 6 and 7, 2004, Plaintiff Nancy Ayers suffered a stroke, which has caused and will continue to cause Plaintiffs to suffer damages, and places Plaintiff Nancy Ayers at risk of further serious injury or death.

38. Unaware of the risks presented by Bextra, or that Bextra was the cause of her injuries, Plaintiff's doctors continued to give her Bextra until December 9 or 10, 2004.

39. Plaintiffs and Plaintiff Nancy Ayers' healthcare providers were, at the time that she was prescribed Bextra, unaware, and could not have reasonably known or have learned through reasonable diligence, that injuries could result from Plaintiff's ingestion of Bextra and Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations.

40. Plaintiff Nancy Ayers used Bextra in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

41. Plaintiffs would not have purchased and Plaintiff Nancy Ayers would not have used Bextra had Defendants properly disclosed the risks associated with the drug, and through diligent effort were not able to discovery the risk from Bextra prior to Nancy's use of the drug.

42. Inclusion of claims in the master complaint does not waive any of the claims for personal injury or otherwise filed by the proposed representative in any individual action already on file.

B. Defendants

43. Defendant Pharmacia is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia has been engaged in the business of marketing and selling Bextra.

44. Defendant Pfizer is a Delaware corporation with its principal place of business in New York. In 2003, Pfizer acquired Pharamcia for nearly $60 billion. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Bextra nationwide.

45. Defendant Searle is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Bextra nationwide.

IV. FACTUAL BACKGROUND

A. Development of Bextra

46. Bextra is one of the new entries in a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen, and ibuprofen are examples of well-known NSAIDs.

47. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are at least two forms of COX enzymes relevant to NSAIDs, COX-1 and COX-2.

48. COX-1 is constitutively expressed in most tissues throughout the body, including the gastrointestinal tract, kidney and platelets.

49. COX-2 is inducible, and is normally found in very low amounts in healthy tissue (except the brain and kidney) but is prominently expressed in inflamed tissues. COX-2 is not expressed in the platelets or the gut.

50. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body's ability to repair gastric tissue and causes harmful gastrointestinal side effects, including stomach ulceration and bleeding. In addition, blocking the COX-1 enzyme decreases the production of thromboxane in platelets, diminishing thromboxane's effect of vasoconstriction and platelet aggregation, and thereby increasing the risk of abnormal bleeding.

51. It is generally accepted in the medical community that selectively blocking the COX-2 enzyme without also blocking the COX-1 enzyme encourages the formation of blood clots and increases the risk of various clot-related cardiovascular events, including heart attack, stroke, unstable angina, and peripheral blood clots.

52. Traditional NSAIDs like aspirin reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach and intestines. However, because of a complex chemical balance in the human

body, traditional NSAIDs do not cause blood clots, and aspirin even reduces the risk of clots and helps protect heart function in some people, an effect commonly referred to as "cardioprotection."

53. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs counteract the GI effect with other medication, or take nothing and live with the pain.

54. Defendants set out to remedy this problem by developing "selective" inhibitors that would block only COX-2 production, and thus the *theory* – although not the clinically proven fact – was that this might allow the proper maintenance of gastric tissue while still reducing pain sensations.

55. In making this decision, Defendants either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels without a counterbalancing reduction in thromboxane production, thereby increasing the risk of blood clots and various clot-related cardiovascular events, including heart attack, stroke, unstable angina and peripheral blood clots.

56. Defendants launched Celebrex, the first of the three major selective COX-2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and consumers of the superiority of the new "blockbuster" drug over less expensive NSAIDs. Merck & Co., Inc. ("Merck") launched Vioxx shortly thereafter and engaged in similarly deceptive advertising and marketing of its new COX-2 inhibitor.

57. Defendants sought approval of a second generation COX-2 inhibitor and filed for FDA approval of Bextra (valdecoxib) on January 16, 2001 for the (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

58. In its pre-approval marketing plans, Defendants assumed that Bextra would be approved and that such approval would include an indication that it was safer than other NSAIDs in protecting against GI complications. The treatment of pain with reduced GI complications was the single most important attribute to the planned marketing and promotion of Bextra and its place as a new blockbuster drug.

59. Pre-approval marketing plans were to stress that Bextra was superior to other NSAIDs in terms of both efficacy and safety, offering a significant reduction in GI complications. Pre-approval marketing plans also anticipated that the FDA would approve Bextra for the treatment of acute pain in adults.

60. In September 2000, Defendants submitted a new drug application for an injectible COX-2, generically named "parecoxib" (a "pro-drug" of Bextra that gets metabolized immediately into Bextra after its administration). In July 2001, the FDA declined to approve parecoxib. In the disapproval letter, the FDA states,

> The safety of parecoxib in the multiple dose setting has not been adequately established. Findings in Study 035 raise the possibility that parecoxib is associated with serious, life-threatening adverse events including myocardial infarction, thrombo-embolic events (such as cerebrovascular accidents, deep venous thrombosis and luminary embolism), pericarditis, upper gastrointestinal injury, and hypotension. Hypoxia, renal dysfunction and hypertension were also experienced more frequently with parecoxib use than the comparator analgesic. All four deaths in the study occurred in the parecoxib treated group.

Defendants ignored this clear cardiovascular signal with a drug almost identical to Bextra and continued their deceptive launch plans.

61. The FDA granted approval of Bextra on November 16, 2001 for two particular uses: treatment of primary dysmenorrhea and relief for the signs and symptoms of osteoarthritis and rheumatoid arthritis.

62. However, the agency did not grant approval of Bextra for the management or prevention of acute pain. In rebuking the effort to obtain such a broad indication for Bextra, the FDA determined that Bextra had not been proven as more effective than other NSAIDs, and that given the ongoing concerns regarding COX-2s generally at that time, broader indications in that class should not be granted. Further, Defendants did not obtain approval to promote Bextra as less likely than other NSAIDs to cause clinically serious GI events, a potentially serious blow to Defendants. As a result, the Bextra package inserts had to include a warning that its use presented "risk of GI ulceration, bleeding, and perforation."

63. The FDA also warned that Bextra had not demonstrated safety and efficacy for opiod sparing, noting,

> …adverse events associated with opiods such as hypotension were seen more frequently in the valdecoxib treated patients. There was no clear evidence of less confusion, somnolence, respiratory depression, nausea and vomiting or constipation to suggest a clinical advantage associated with the lower does of opiod used. The clinical benefit of post-operative co-administration of fixed dosing of valdecoxib and ad lib opiod dosing has not been demonstrated.

As described in detail below, Defendants ignored these warnings and limitations on the indications for Bextra and falsely touted it as a powerful pain reliever with opioid sparing benefits.

64. The original label for Bextra also contained the following precautions relating to the cardiovascular risks associated with Bextra:

> **Renal Effects**
>
> Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of a nonsteroidal anti-inflammatory drug may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and Angiotensin Converting Enzyme (ACE) inhibitors, and the elderly.
>
> …
>
> **Fluid Retention and Edema**
>
> Fluid retention and edema have been observed in some patients taking BEXTRA (see ADVERSE REACTIONS). Therefore, BEXTRA should be used with caution in patients with fluid retention, hypertension, or heart failure.

The label warned of particular interactions with other medicines, including,

> ***Aspirin***: Concomitant administration of aspirin with valdecoxib may result in an increased risk of GI ulceration and complications compared to valdecoxib alone. Because of its lack of anti-platelet effect valdecoxib is not a substitute for aspirin for cardiovascular prophylaxis.

The ADVERSE REACTIONS section of the original label warned that adverse CV events including, aggravated hypertension, aneurysm, angina pectoris, arrhythmia, cardiomyopathy,

congestive heart failure, coronary artery disorder, heart murmur, hypotension, bradycardia, palpitation, and tachycardia had been observed in patients treated with Bextra.

65. Even though the Defendants were required to market Bextra only as described in the FDA approved label, they marketed Bextra's safety and efficacy as far superior than the information that appeared in its labeling. For example, in a February 2002 letter from the FDA to Pharmacia, the FDA reviewer found multiple misleading claims in the launch advertisements submitted. The FDA warned, "[y]our proposed detail aid is misleading because it contains claims that overstate the effectiveness of Bextra" and stated that claims made in the same detail aid were "misleading because these efficacy claims have not been demonstrated by substantial evidence."

66. In the same letter, the FDA reviewer specifically criticized Pharmacia's "misleading presentations" including, (1) presentation of data that had not been sufficiently replicated, (2) selective presentation of the most positive results and failure to include results that were not favorable, (3) presentation of data from a prospective subgroup analysis, when the original study did not contemplate analysis of the data in such subgroups, falsely producing positive results, (4) pooling of data from trials that were not designed with the endpoints the defendants presented, (5) use of theoretical models that had not been demonstrated by substantial evidence, (6) unbalanced presentation of benefits versus risks, specifically, portraying benefits in bold, large type at the top of the ad and risks in small, light type at the bottom of the ad. Although Defendants were provided this direction prior to the launch of Bextra, they ignored it and proceeded to use all of the above misleading marketing techniques throughout Bextra's reign in the market.

67. Almost three years later, in January 2005, the FDA continued to criticize Defendants misleading marketing methods. In response to submitted promotional pieces for Bextra and Celebrex, the FDA commented generally,

> [t]hese five promotional pieces variously: omit material facts, including the indication and risk information; fail to make adequate provision for the dissemination of the FDA-approved product labeling; and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims. They are, therefore, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and FDA implementing regulations.

The letter pointed out that a particular advertisement, "arthritis tips TV ad" was not even submitted to the FDA as required by federal regulations. The letter went on to warn,

> [t]he omission or minimization of risk information in these promotional materials is a public health concern because Celebrex and Bextra are contraindicated for several patient populations, both products contain warnings of serious gastrointestinal (GI) effects and anaphylactoid reactions and Bextra contains an additional warning regarding serious, possibly life-threatening skin reactions.

The letter called attention to the numerous potential risks stated in both drugs respective labels, but lacking in the Defendants advertisements, including,

> [s]pecific warnings related to: gastrointestinal (GI) effects, including risks of GI ulceration, bleeding and perforation; hypersensivity reactions including anaphylactoid reactions and angioedema; use in patients with advanced renal disease, due to lack of controlled clinical studies regarding use of the products in this population; and use in patients with preexisting asthma.

The letter concluded that the violations it discusses are of a "serious nature" and Defendants should "act to avoid disseminating similarly misleading promotion[s]…in the future." The Defendants are further warned that the violations discussed in the letter are not an "exhaustive list" and that "[i]t is [Defendants'] responsibility to ensure that your promotional materials for Celebrex and Bextra comply with each applicable requirement of the Act and FDA implementing regulations."

68. Defendants coolly responded that they disagreed with the FDA's interpretation of the advertisements. Instead of immediately halting the advertisements or the misleading methods highlighted by the FDA, Defendants explicitly told the FDA that they would "consider DDMAC's comments" when developing advertisements in the future.

B. Studies on Bextra and Other COX-2 Inhibitors

69. Based on studies performed on Celebrex, Vioxx, Bextra, and other COX-2 inhibitors, Defendants knew by 1998 that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

70. For example, in an effort to demonstrate that Celebrex had greater gastrointestinal safety than traditional NSAIDs, Defendants funded a clinical trial, the results of which were published in 2000: the Celecoxib Long-Term Arthritis Safety Study ("CLASS"). Defendants

expected CLASS to show that Celebrex produced significantly fewer serious GI complications than traditional NSAIDs.

71. The CLASS trial was a long-term, double-blind study of gastrointestinal toxicity in 8,059 patients taking Celebrex, ibuprofen, or diclofenac to treat arthritis. Patients with heart problems were allowed to participate in the CLASS trial, and were permitted to take low doses of aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

72. When the CLASS study was completed, the results were reported to the U.S. Food and Drug Administration's Arthritis Drugs Advisory Committee (the "Committee") as part of a request to exempt Celebrex from including a gastrointestinal safety warning in its package insert. After reviewing the CLASS results, however, the Committee concluded that patients taking Celebrex had not experienced fewer gastrointestinal complications than those taking traditional NSAIDs. Moreover, the CLASS study demonstrated a trend toward cardiovascular risks for those taking the selective COX-2 inhibitor Celebrex.

73. A post hoc analysis and comparison of CLASS study patients taking low-dose aspirin for cardiac protection and patients not taking low-dose aspirin revealed that the rate of combined anginal adverse events was 1.4% in the celecoxib (Celebrex) group versus 1.0% in the ibuprofen and diclofenac groups. Although not a statistically significant difference, this tendency towards increased cardiovascular toxicity was described by the FDA Medical Officer Dr. Witter, who stated that "[f]or anginal disorders (especially the combined disorders), there seems to be a trend toward more [cardiac adverse] events in those patients receiving celecoxib, regardless of aspirin use."

74. This trend was magnified in those patients not taking low-dose aspirin. Combined anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0% in the diclofenac and ibuprofen groups, respectively. There were also more combined atrial serious cardiac adverse events with celecoxib, 0.3% compared to 0.1% and 0% in the diclofenac and ibuprofen groups, respectively. Dr. Witter commented that "[i]n the non-aspirin users, there appears to be a slight trend toward more [serious cardiac adverse] events in those patients receiving celecoxib for combined atrial and anginal disorders." Additionally, the rate of myocardial

infarction was higher in the celecoxib group, 0.2%, compared with the other two drugs, 0.1%. Dr. Witter also referred to data from the original New Drug Application ("NDA") for celecoxib in his discussion, stating that "[t]here were suggestions of a dose-response relationship (… 100 mg BID celecoxib, 0% crude mortality rate vs. 400 mg BID celecoxib, 0.64% crude mortality rate) between cardiovascular mortality and [increased] celecoxib use that could not be adequately addressed by the data."

75. The FDA was concerned enough that they ordered a cardiorenal consult by Medical Officer Dr. Throckmorton on the same CLASS study data. In his report he noted, "[t]he CLASS trial data do not support a large adverse effect of celecoxib on cardiovascular mortality or on serious adverse events related to thrombosis relative to either diclofenac or ibuprofen. The data do not exclude a less apparent pro-thrombotic effect of celecoxib, such as might be reflected in the relative rates of cardiac adverse events related to ischemia."

76. While none of the CLASS data was statistically significant, they revealed a consistent and worrisome trend toward increased cardiovascular toxicity, particularly with regard to increased thrombosis.

77. Importantly, the reviewers recommended that "[o]ur findings suggest a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors… definitive evidence of such an adverse effect will require a prospective randomized clinical trial… Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents. Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular morbidity." Although employing a placebo group from a different trial weakens the validity of their analysis, the author's call for a prospective randomized clinical trial powered to truly analyze the cardiovascular risk to benefit ratio was then exactly correct. A subsequent placebo-controlled trial of celecoxib clearly demonstrated this risk.

78. The subsequent trial was the APC colon polyp recurrence prevention study, in which approximately 2000 patients took celecoxib or a placebo. Interestingly, this was the longest celecoxib trial to date with mean duration of treatment being 33 months as opposed to the much

shorter 12-month duration of the CLASS study. A statistically significant elevation in the risk of major fatal or non-fatal cardiovascular events (a composite endpoint of cardiovascular death, acute myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in the placebo group. This followed a dose-response relationship: the relative risk at 400 mg/day of celecoxib was 2.5 while the relative risk at 800 mg/day was 3.4. Because of this unacceptable danger, the trial was prematurely halted. The FDA released an explanatory statement which said, "[w]hile we have not seen all available data on Celebrex, these findings are similar to recent results from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently voluntarily withdrawn by Merck."

79. Merck had previously conducted a large-scale, long-term, double-blind study of gastrointestinal toxicity in patients taking Vioxx or naproxen to treat arthritis. This study came to be called the Vioxx Gastrointestinal Outcomes Research study ("VIGOR").

80. Merck designed VIGOR to produce the absolute minimum number of cardiovascular events by excluding patients with (a) a history of heart attack or coronary artery bypass surgery within the past year; (b) a history of stroke or transient ischemic attack within the past two years; or (c) or those who "required or who had been receiving treatment with aspirin," effectively excluding patients with a history of coronary artery or cerebrovascular disease. Despite being designed so that participants would have far less cardiovascular disease than the normal population taking NSAIDs and thereby minimizing the apparent cardiovascular risk of Vioxx in comparison to naproxen, the VIGOR results still showed that patients taking Vioxx suffered more than twice the number of serious thrombotic cardiovascular events and five times the number of heart attacks as patients taking naproxen.

81. In October 2000, Merck sent its cardiovascular data from the VIGOR trial to the FDA for review. In February 2001, the FDA published a Memorandum on the Vioxx cardiovascular safety data gathered during VIGOR. In this Memorandum, the FDA concluded that there "is an increased risk of cardiovascular thrombotic events, particularly [heart attack], in the [Vioxx] group compared with the naproxen group." The FDA considered and rejected all defenses raised by Merck to explain the statistically significant increase of cardiovascular incidents among

Vioxx users. In February 2001, the FDA also concluded that Merck should have to add a cardiovascular warning to its Vioxx packaging: "it would be difficult to imagine inclusion of VIGOR results in the [Vioxx] labeling without mentioning cardiovascular safety results in the study description as well as the Warnings sections."

82. In August 2001, independent doctors from the Cleveland Clinic performed their own meta-analysis of the Celebrex and Vioxx clinical trials on the issue of cardiovascular safety. Their findings "suggest a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors." Based on their findings and the widespread use of COX-2 inhibitors, these doctors concluded "that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents."

83. In light of these studies and FDA findings, Defendants were well aware of the serious cardiovascular risks posed by selective COX-2 inhibitors, including Bextra, long before Defendants began marketing Bextra as being safe and more effective than traditional NSAIDs for all patients, without regard for cardiovascular risks.

84. Studies show that COX-2 inhibitors, including Bextra, decrease production of a cardioprotective substance called prostacyclin. When prostacyclin synthesis is suppressed the arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

85. Label changes implemented in November 2004 reflected the growing scientific data that Bextra and parecoxib posed serious cardiovascular risks. A contraindication was added for the treatment of post-operative pain immediately following coronary artery bypass graft surgery based on the results of three placebo-controlled studies (two coronary artery bypass graft (CABG) surgery studies and one general surgery study) that were conducted to evaluate the safety of Bextra and parecoxib. As reflected in the new labeling, results of the first CABG study ("CABG I") showed,

> a significantly ($p<0.05$) greater incidence of cardiovascular/thromboembolic events (myocardial infarction, ischemia, cerbrovascular accident, deep vein thrombosis and pulmonary embolism)…in the parecoxib/vadecoxib treatment group compared to the placebo/placebo treatment group for the IV dosing period (2.2% and 0.0% respectively) and over the entire study period (4.8% and 1.3% respectively).

CABG I results also revealed an increased rate of surgical wound complications in patients treated with valdecoxib and parecoxib.

86. The results of CABG II, as reflected in the new label, emphasized these cardiovascular risk concerns. CABG II revealed,

> [a] significantly…greater incidence of events in the cardiovascular/thromboembolic category…in the parecoxib/valdecoxib treatment group (2.0%) compared to the placebo/placebo treatment group (0.5%). Placebo/valdecoxib treatment was also associated with a higher incidence of CV thromborembolic events versus placebo treatment, but this difference did not reach statistical significance.

Although the third general surgery study did not reveal significant differences in the overall safety profile of the comparators, the FDA found the data as a whole compelling enough to include the new contraindication for CABG patients in the labeling.

87. Another new addition to the label, entitled "Cardiovascular Safety Analysis from Osteoarthritis and Rheumatoid Arthritis Studies," explains that although "no apparent differences were detected in the exposure-adjusted serious cardiovascular thromboembolic event rates between patients receiving BEXTRA, placebo and NSAIDs," Bextra has not been studied in controlled clinical trials longer than one year and the clinical studies that have been conducted were not powered to detect differences cardiovascular events in a chronic setting.

88. The FDA also required the strengthening of warnings about the risk of life-threatening skin reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis. Stevens-Johnson Syndrome is marked by blistering lesions on the body, prone to rupture and secondary infection, and has been described as burning from the inside out. Patients with toxic epidermal necrolysis, also known as TENS, develop multiple large blisters, followed by the sloughing of the skin and mucous membranes.

89. By November 2004, the FDA had received nearly ninety reports of such severe skin reactions, some of which resulted in hospitalization and death. While other NSAIDs also pose a risk for rare, serious skin reactions, the reported rate of such side effects was vastly higher in individuals taking Bextra.

90. In mid-January 2005, an editorial in *Circulation* combined the results of two studies of Bextra and parecoxib in post-cardiac bypass surgery patients (separate from the studies described above). The results showed that those taking Bextra and parecoxib developed three times more heart attacks and strokes (statistically significant) than those given a placebo.

91. In February 2005, WellPoint, Inc., the nation's largest provider of health care benefits, released a study it conducted in conjunction with researchers at Indiana University's medical school on the risks of cardiovascular events in patients taking COX-2 inhibitors. The study involved the records of more than 635,000 patients and demonstrated that COX-2 inhibitors do increase the risk of adverse cardiovascular events. However, while Vioxx increased patients' risk of heart attack and stroke by approximately 20%, Bextra increased the risk by 50%. Dr. Sam Nussbaum, WellPoint's executive vice president and chief medical officer, noted that the study was further evidence of an "increasingly compelling trend" of data showing that COX-2 inhibitors elevate patients' risk of adverse cardiovascular events.

92. From February 16-18, 2005, the FDA's Drug Safety and Risk Management Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham stated that COX-2 inhibitors increase the risk for adverse cardiovascular events at about the same rate as cigarette smoking, hypertension, and diabetes.

93. A paper published in the December 4, 2004 LANCET found, after analyzing 18 randomized controlled trials and 11 observational studies, that by the year 2000 these studies showed an increased risk of myocardial infarction from use of Vioxx and that it should have been withdrawn years earlier. Pfizer was aware of each of these studies and should not have advertised Bextra as generally safe.

94. An Australian study released in March 2005 analyzed results from all nineteen randomized controlled trials of COX-2 inhibitors published before May 2004 and found that those studies indicated that individuals taking COX-2 inhibitors, including Bextra, had a 60% higher chance of elevated blood pressure compared with those on a placebo.

95. Despite years of studies on COX-2 inhibitors, as well as disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any action to protect the health and welfare of patients and instead continued to promote the CV safety of Bextra.

96. On April 7, 2005, the FDA requested that Defendants voluntarily withdraw Bextra from the market, stating:

> …the Agency has concluded that the overall risk versus benefit profile of Bextra is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that Bextra has not been shown to offer any unique advantage over the other available NSAIDs.

FDA Alert for Healthcare Professionals, April 7, 2005.

97. Continuing, the FDA noted:

> Bextra has been demonstrated to be associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery…. FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for Bextra from the short-term CABG trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding…. To date, there have been no studies that demonstrate an advantage of Bextra over other NSAIDs that might offset the concern about the[] serious skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.

Id.

98. Pfizer agreed to suspend sales of Bextra, and Bextra has been withdrawn from the market as of April 7, 2005.

C. Marketing and Promotion

99. Despite knowing (i) that Bextra posed serious cardiovascular risks for anyone who took it, along with the risk of a death-causing skin disease, (ii) that Bextra provided no clinically proven improvement over pain relief for OA and RA, (iii) that Bextra was not indicated for the treatment of acute pain and (iv) that Bextra provided no clinically proven improvement for GI

safety, Defendants made a business decision to push Bextra to market on claimed improvements in GI and CV safety, while downplaying its skin dangers.

100. Defendants initiated extensive marketing campaigns to convey the uniform message that Bextra provided effective pain relief without the gastrointestinal and cardiovascular side effects of other NSAIDs. Such claims were not permitted by the FDA. Defendants also falsely promoted Bextra as safe by downplaying or omitting the serious skin risks posed by use of the drug. Defendants pursued this strategy to benefit from the assumption that, in the absence of information to the contrary, Bextra possessed the same skin dangers as traditional NSAIDs.

101. Defendants' advertising efforts included blitzing doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Bextra was a superior drug for treatment of osteo- and rheumatoid arthritis and primary dysmenorrhea. They aggressively promoted Bextra as an improvement over older, less expensive NSAIDs, like naproxen and ibuprofen, claiming it had a lower risk of gastrointestinal side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote or provide any balanced presentation as to Bextra having an unacceptably high risk of other side effects, such as heart attacks, strokes, unstable angina, cardiac clotting, hypertension, and severe skin reactions.

102. Such marketing efforts to physicians have become commonplace in recent years. Drug companies pay national and local "thought leaders" or "key opinion leaders," including local specialists, to speak at continuing medical education events that promote the use of expensive new drugs such as Bextra. In addition, drug companies – with Pfizer in the forefront – spent billions on "detailing" to physicians – *i.e.*, having their sales representatives visit doctors in their offices, frequently bringing gifts and lunch, to "educate" doctors about their companies' drugs.

103. The deceptive marketing techniques that Pfizer employed through "thought leaders" are apparent in an internal summary document of a November 2001 advisory committee meeting regarding the marketing of Bextra. Even though Defendants received feedback at the meeting from its advisors that "CV concerns with Bextra seem real, considering: · 92% of OA patients in study #047 developed hypertension · Hypertensive patients undergoing CABG have higher incidence of MI," they also received the following marketing feedback:

> Do not draw unnecessary attention to CABG data by communicating about it too much.
>
> …
>
> [It is] [h]ard to position Bextra for pain and Celebrex for arthritis, when labeling positions Bextra for arthritis not pain – ***marketing plan is out of sync with the label.***
>
> …
>
> Physician education will be crucial to explain why Bextra should be used instead of other NSAIDs when the product has no pain indication · ***Pain data must be disseminated via medical education initiatives.***
>
> …
>
> Publish BEXTRA acute pain abstracts soon and often. It sends a powerful message.

(emphasis added). Defendants clearly heeded this advice and did exactly as recommended by (1) downplaying any cardiovascular safety signals by not raising or avoiding negative data, even though such data was in sync with the cardiovascular risks noted in the Bextra label, (2) marketing Bextra for acute pain, an indication for which it was not approved, and (3) avoiding the limits placed on Bextra's marketing by the FDA labeling by providing one sided pain data to doctors under the guise of "medical education."

104. The Defendants marketed Bextra for use in the treatment of pain, contrary to its FDA approved labeling, directly to doctors. In a summary document of "Final Evaluations" from the 2002 National Consultant's Meeting for Orthopedic Surgeons organized by Defendants, participant responses to the question "which specific information presented did you find most compelling," included,

> · Valde[coxib] used as pain med.
>
> · Pain data – synergy of multimodal therapy
>
> · Safety & efficacy of Celebrex & Bextra
>
> …
>
> · Gastrointestinal safety profile of COX-2 inhibitors
>
> …

> · Although Bextra doesn't have a pain indication, it is effective in pain management
>
> · Use of Bextra as a pre-op adjunct and post op for management of pain…

The physician responses establish that Defendants were ignoring the FDA indications for Bextra and moving forward with their marketing strategy, falsely marketing Bextra as generally safe and effective especially for GI and promoting it for pain even though the FDA refused to approve it for the treatment of pain.

105. At meetings with analysts, Pfizer revealed its marketing strategy and the message it was conveying to medical providers for the use of Bextra, as reported in a December 21, 2001 report published in ESPIcom Business Intelligence Ltd:

> Pfizer also received regulatory approval for Bextra, a second-generation Cox-2 inhibitor for the treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and menstrual pain. Co-promoted with Pharmacia, Bextra is a new, once-daily option for people with OA and RA. It offers improved gastrointestinal toleration with no increase in renal or cardiovascular risk versus traditional NSAIDs.

106. In this and other press releases and promotional devices Defendants falsely promoted the GI and CV superiority of Bextra as compared to other NSAIDs.

107. Based on information supplied by Pfizer, the following appeared in the August 9, 2003, CHEMIST & DRUGGIST:

> Bextra is a new… Cox-2 inhibitor from Pfizer indicated for treatment of symptoms of osteoarthritis and rheumatoid arthritis as well as dysmenorrhoea. In clinical trials it showed similar efficacy to maximum doses of naproxen, ibuprofen and diclofenac, but has a lower incidence of gastroduodenal ulcers than the traditional NSAIDs. Bextra contains valdecoxib, a Cox-2 enzyme inhibitor.

108. Based on information supplied by Pfizer the following appeared in COMMUNITY PHARMACY on July 21, 2003:

> Bextra (valdecoxib), from Pharmacia, is a new cyclooxygenase-2 (Cox-2) selective inhibitor, indicated for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA) and primary dysmenorrhoea. In the UK, 20 million people have an arthritic condition and up to pounds 920 million, excluding indirect costs, is spent annually on their care. **Bextra** offers a powerful alternative to maximum doses of the traditional non-steroidal anti-inflammatory drugs (**NSAIDs**), diclofenac, naproxen and ibuprofen in OA and RA, and a powerful alternative to naproxen sodium for those patients

> suffering pain associated with primary dysmenorrhoea, says the company. ***Additionally, being selective it largely avoids gastrointestinal side effects.*** (Emphasis added.)

109. The following was published at the request of Pfizer in THE PRACTITIONER on July 7, 2003:

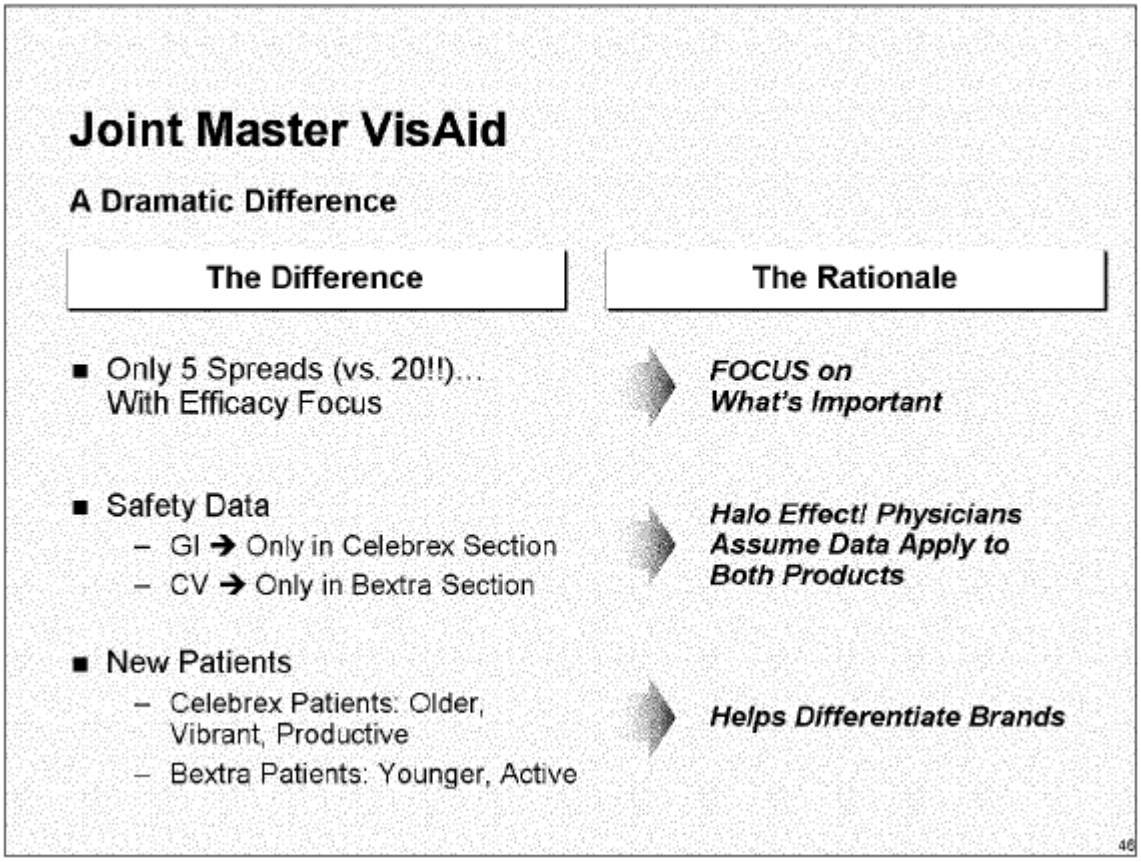
> **Bextra** is a fast-acting oral COX-2 selective inhibitor for the treatment of osteoarthritis, rheumatoid arthritis and primary dysmenorrhoea, and was developed to offer an alternative to maximum dose traditional **NSAIDs**. The recommended dose in arthritis is 10mg once- daily, although some patients may benefit from a 20mg dose daily. Patients suffering from menstrual cramps are recommended to take 40mg doses.

110. On or about May 19, 2003, Pfizer issued the following statement:

> Pfizer Inc Receives Approval to Market New Oral COX-2 Inhibitor Bextra (Valdecoxib) in Europe
>
> Pfizer Now Offers the Widest COX-2 Inhibitor Portfolio
>
> NEW YORK, May 19 – Pfizer Inc said today that it has received approval to market Bextra(R) (valdecoxib) film coated tablets, the newest COX-2 selective inhibitor in its portfolio, in Europe for treatment of patients with pain and inflammation associated with osteoarthritis (OA), rheumatoid arthritis (RA) and primary dysmenorrheal (painful menstrual cramping).
>
> Valdecoxib received marketing authorization from the European Commission with labeling that is valid in all 15 European Union (EU) member states, and the approval will be extended to Norway and Iceland. This approval allows Pfizer to offer the widest portfolio of COX-2 selective inhibitors in Europe.
>
> "We are pleased with the EU Commission decision to approve Bextra and look forward to offering patients and physicians a new option for treating osteoarthritis, rheumatoid arthritis and primary dysmenorrheal," said Dr. Jack Watters, Pfizer's Vice President, Medical and Regulatory, Europe and Canada. "COX-2 selective inhibitors are an innovative class of medicines specifically developed to relieve pain and inflammation as effectively as widely used conventional non-steroidal anti-inflammatory drugs, ***while offering an improved upper gastrointestinal safety profile***," he added. (Emphasis added.)

111. Each of the foregoing releases was designed to create demand for Bextra by those making decisions concerning the use of Bextra by patients. Each of the foregoing were just examples of dozens of such marketing ploys disseminated by Defendants.

112. Another of Defendants' marketing ploys was to detail Bextra along side of Celebrex, revealing only the positive data for each drug so that doctors would think that the positive data actually applied to both drugs. The Defendants referred to this marketing strategy as the "Halo Effect." The Halo Effect is contrary to the FDA approved labeling for both drugs in that it promoted each drug with data that had no scientific connection whatsoever to that drug. Defendants' employment of the Halo Effect shows a clear lack of fair balance in the Defendants' detailing methods – ignoring the risks of one drug and touting its benefits. As revealed in the sales training presentation below, the Halo Effect was taught as a technique for marketing both drugs. Such selective presentation of safety data was contrary to the FDA approved labeling.



113. Another of Defendants' marketing and promotional devices that was deceptive and contrary to its FDA approved labeling was the funding of research designed to falsely produce

positive outcomes with Bextra usage. These findings were then published in medical journals and distributed via press releases and other public relations techniques to medical and non-medical media, targeted at doctors, the public and others in the drug purchasing decision chain. During the Class Period, these paid researchers touted the safety of Bextra. For example, the following doctor was quoted in a Pharmacia press release, dated November 27, 2002, as follows:

> "Our analysis suggests that valdecoxib shows no greater incidence of cardiovascular events than either naproxen or placebo," said lead author Andrew Whelton, M.D., adjunct professor of Medicine, Johns Hopkins University, Baltimore, Maryland. "While more data are necessary to confirm this conclusion, our findings suggest that valdecoxib demonstrates a cardiovascular safety profile similar to that of placebo or naproxen."
>
> According to Whelton, "Whether patients were or were not taking aspirin did not significantly impact the incidence of serious adverse events."

114. Such a claim is not permitted by the FDA label or within the scope of FDA approval.

115. Another example of Defendants' deceptive marketing is the republication, in a press release issued on August 1, 2002, of the results of a study in the JOURNAL OF OBSTETRICS AND GYNECOLOGY purporting ***to show that Bextra was more effective than Naproxen for treatment of pain during menstruation***. The study compared Bextra 40 mg twice daily (BID) as needed, Bextra 20 mg BID as needed, naproxen sodium 550 mg BID as needed, to placebo for up to 3 days for the treatment of pain associated with menstruation (dysmenorrheal). The maximum dose of Bextra approved by the FDA for the treatment of primary dysmenorrhea was up to 20 mg BID per day. On every measure of pain relief, naproxen sodium 550 mg provided better pain relief than Bextra 20 mg BID (some of the differences achieved statistical significance). Furthermore, patients taking Bextra 20 mg BID experienced more than twice as many of the most common side effects as did the patients taking naproxen sodium 550 mg BID. In other words, Bextra provided inferior pain relief, caused more side effects, and cost far more than naproxen sodium – it's hard to understand how this data could be used to make the case that Bextra was the superior choice – but that is just what Defendants did. SCIREX Clinical Research Center, a company owned in part by OMNICON, one of the largest advertising agencies, was hired by Pfizer to conduct this study. Pfizer reprinted

parts of the study, omitting the known risks of cardiovascular and skin disorders. Again, any claims of pain superiority over other drugs was not permitted by the FDA label.

116. Defendants also used SCIREX, to promote Bextra via an article and an accompanying continuing education quiz published in the JOURNAL OF THE AMERICAN DENTAL ASSOCIATION. The study, featured by Pharmacia in a press release dated May 8, 2002, purported to show Bextra's superiority for use in pain relief. No disclosure was made of the researchers' financial ties to Pharmacia or to the known adverse effects associated with Bextra. One of the three scientific reviewers of the paper – an associate editor of the journal – told the NY Times that, had he known that Bextra had not been approved by the FDA for relief of dental pain, he would have recommended the paper be rejected. As it was, the paper was published in the journal, along with a continuing education quiz to reinforce the message that Bextra is helpful for post-dental surgery pain, an indication for which Bextra was not approved.

117. These and similar studies helped increase the acceptance of Bextra by medical and dental providers.

118. The Defendants also targeted consumers directly with false marketing claims regarding Bextra. Some of the methods they used to reach consumers included leaving patient directed brochures at doctors' offices and providing marketing materials to doctors that could be distributed to their patients. Defendants also maintained websites and a toll free telephone number that conveyed misleading information regarding the safety and efficacy of Bextra. As noted in an internal memorandum, "there are several successful programs in the market now with proven value in generating consumer demand for Bextra (e.g. TIME/PEOPLE Coverwrap MD Office program, PERFORM magazine, In Office brochure) and this POA we will shortly roll out the very successful unbraded "On the Road to Pain Relief" long format (30min) direct response TV ad."

119. As referenced above, the use of "unbranded" advertising is another all too common and sophisticated method of advertising that Defendants used to market Bextra to consumers. It is also a method of advertising that Defendants hoped would shield them from responsibility for false claims conveyed. As one of Pfizer's sales managers describes in October 2004, immediately after the withdrawal of Vioxx, "[w]e are currently running an unbranded long-format ad as well as a 60-

second ad about arthritis symptoms and appropriate treatment options. Consumers who respond to these advertisements receive branded information on CELEBREX and/or Bextra." Thus, the "unbranded" advertisements were clearly used to market Celebrex and Bextra directly to consumers.

120. After the withdrawal of Vioxx, and just one day before the Celebrex APC trial was halted because of CV safety concerns, Defendants produced a document entitled "US Field Force Selling Objections and Answers." The document warns that it is "Company confidential," "for internal use only," "DO NOT DETAIL" and "This document is provided to you for your background information only," but then goes on to describe how to respond to "objections health professionals may raise regarding Bextra." The first question and answer highlight how the Bextra sales force was trained to promote the CV and GI safety of Bextra, even in the face of scientific evidence to the contrary:[5]

> Q1: How can I prescribe Bextra when patients with arthritis often have increased CV risk?
>
> A: Bextra still can be administered safely to patients with arthritis. In a large pooled analysis of 10 arthritis trials in which almost half the patients had at least 1 coronary risk factor, there were no apparent differences detected in the serious CV thrombotic event rates between patients receiving Bextra, placebo, and nonspecific NSAIDs. In this analysis, 13% of patients were taking daily low-dose aspirin, with no increase in CV risk with Bextra. While Bextra is contraindicated for the treatment of postoperative pain following coronary artery bypass graft, or CABG, surgery, it remains an effective and safe treatment for vast number of patients with arthritis who need pain relief along with superior GI safety.

121. Thus, as reflected above, the Defendants instructed their sales force to market Bextra in a manner that the FDA had not approved and in direct contradiction to the approved FDA labeling.

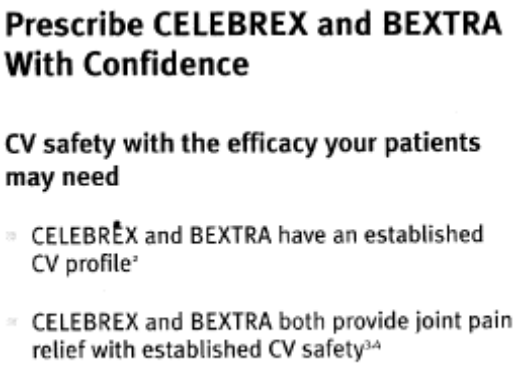
122. In another "objection response" in the same document, Defendants again tout the GI superiority of Bextra, again in direct contradiction to the FDA approved labeling:

> Q1: How can I prescribe Bextra when it is so difficult to get reimbursement for COX-2 specific inhibitors?

[5] The entire document from which this is excerpted is attached hereto as Exhibit 1.

> The formulary status for Bextra has not changed dramatically. And several managed care plans may be using the latest developments as a reason to question the clinical value and appropriateness of the COX-2 specific inhibitor class. However, managed care plans do realize that only physicians know the appropriate therapy for their patients. Because the risk of GI bleeding remains a serious issue with nonspecific NSAIDs, treatment guidelines still stress COX-2 specific inhibitors as first-line treatment for patients at GI risk. Consequently, managed care plans will continue to reimburse for drugs such as COX-2 specific inhibitors as long as physicians confidently affirm that these medications are medically necessary and appropriate for their patients.

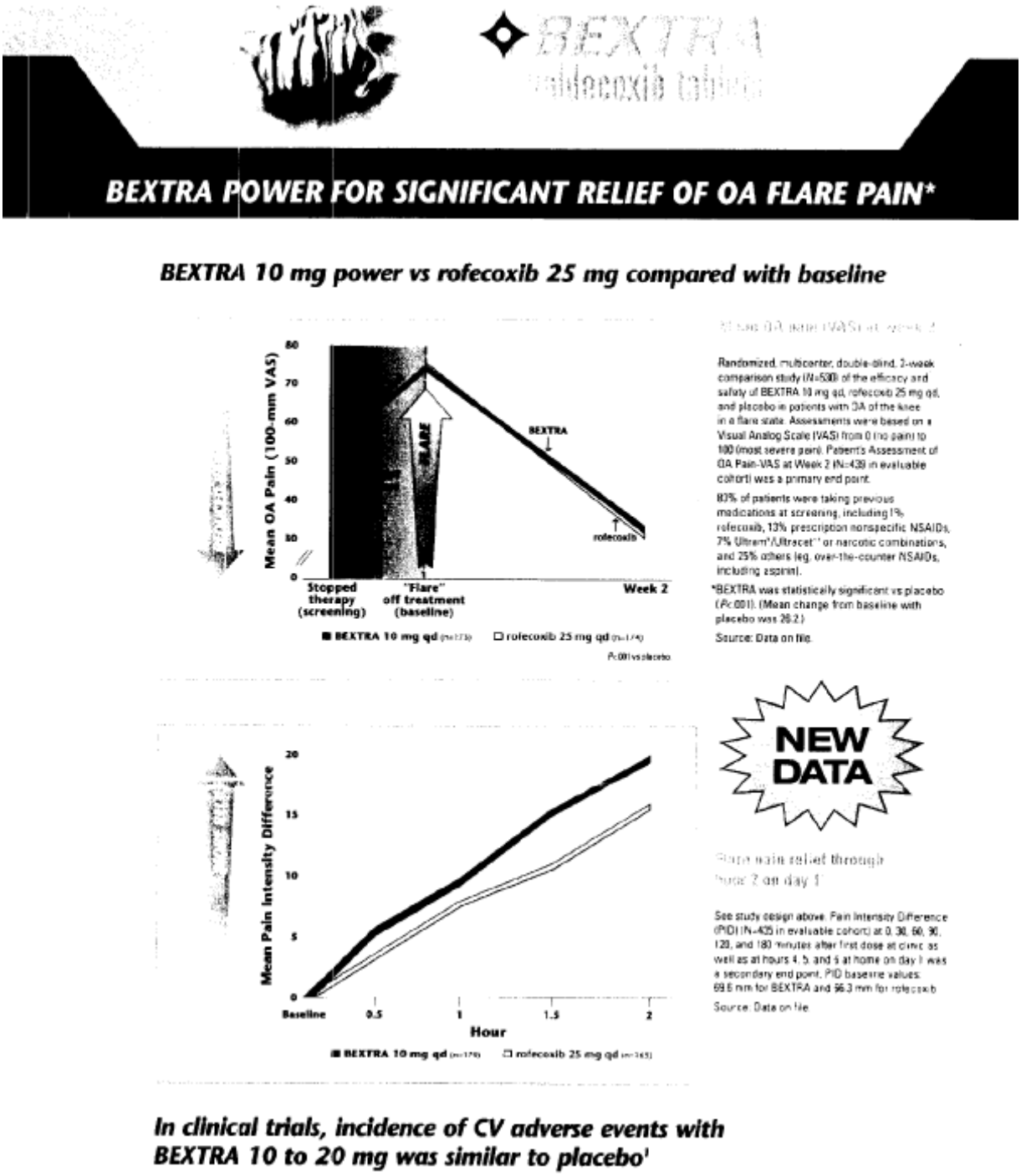
123. Defendants' false promotions of the cardiovascular safety and superiority of Bextra are evident in the following advertisement. In the advertisement, doctors are falsely reassured that they can safely prescribe Bextra because of its "established CV profile," even though no such established CV profile existed and no such profile appears in the FDA approved labeling. Furthermore, the bold statement "Prescribe CELEBREX and BEXTRA With Confidence" implies that absolutely none of the risk information contained in the FDA approved labeling even exists. Such advertising is deceptive and contrary to the FDA approved label for Bextra.[6]



124. The Defendants strategically placed comments on the CV safety of Bextra with claims of superior efficacy. In the following advertisement, Defendants imply that there is no CV risk with Bextra because in unspecified "clinical trials," the incidence of CV events is similar to a placebo. Such a claim lacks fair balance, since it implies that there are no clinical trials in which CV events are higher as compared to placebo – which there were – and is in direct contradiction to

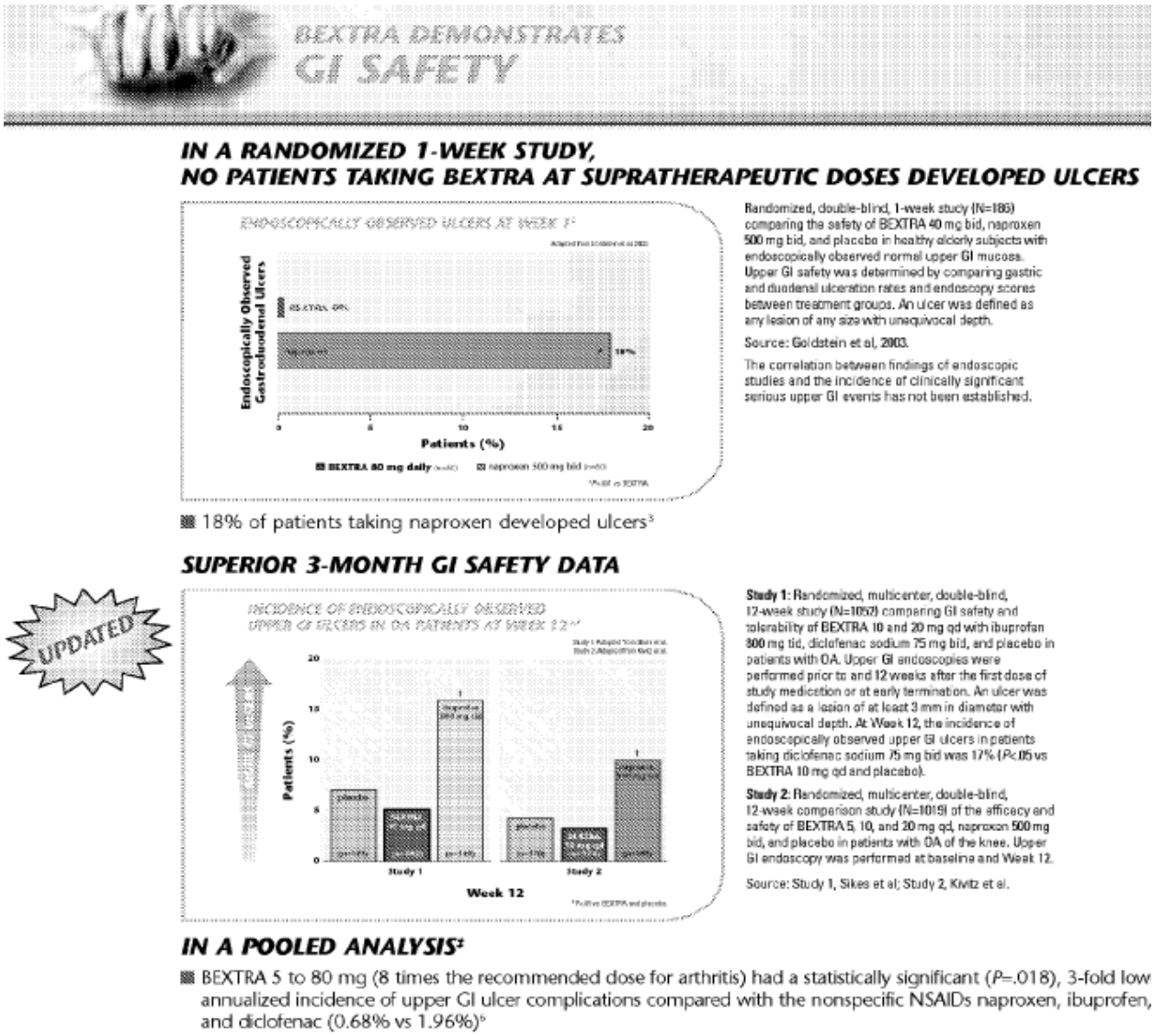
[6] The excerpt above appears at bates number Cele NDA 20-99800022356 of Defendants' document attached hereto as Exhibit 2.

the FDA approved labeling. The footnote after the false CV claim leads a reader to the dead end "Data on file, Pfizer Inc., New York, NY," and hence, does not cure the deceptive presentation.[7]



[7] The referenced excerpt appears at bates number Bex NDA 21-341 00013129 of Defendants' document attached hereto as Exhibit 3.

125. In this December 2004 ad, Bextra was falsely promoted, contrary to its FDA approved labeling, as having "SUPERIOR 3-MONTH GI SAFETY DATA" and deceptive data was presented as "POOLED ANALYSIS" in support of that claim. In a January 2001 letter, however, the FDA scolded Defendants about the continuous onslaught of misleading advertisements and advertising methods, stating, "[w]e are not aware of any evidence showing that Celebrex or Bextra has superior effectiveness to non-selective NSAIDs."[8]



[8] The image above appears at bates number Litwac-A 10000617953 in Defendants' document attached hereto as Exhibit 4.

126. The same detailing brochure contains this false pronouncement of the "CARDIORENAL SAFETY PROFILE" of Bextra. The graphic used include deceptive pooled analyses of data and includes partial and small print risk information that fails to present a fair balance of the risks associated with Bextra as detailed in its FDA approved labeling.[9]

[9] The image above appears at bates number Litwac-A 10000617955 of Defendants' document attached hereto as Exhibit 5.

127. Each of the foregoing advertisements was designed to create demand for Bextra by those making decisions concerning the use of Bextra by patients. Each of the foregoing were just examples of dozens of such marketing ploys disseminated by Defendants either orally to doctors or in written material.

D. Risks Posed by Bextra

128. Despite the effectiveness of their advertising campaigns, Defendants' false promotion of Bextra by touting it as GI and CV safe and downplaying its risk of severe skin reactions did not quell concerns about selective COX-2 inhibitors in the medical community.

129. In 1997, the link between COX-2 inhibition, prostacyclin levels, and blood clotting was receiving attention in medical journals.

130. In 1998, independent doctors established a link between selective COX-2 inhibitors and increased blood clotting, and suggested that these drugs would cause an increase in clot-related cardiovascular events. These doctors suggested that these drugs should not be given to patients with known cardiovascular disease, and that patients taking these drugs would have to be monitored for cardiovascular complications.

131. The cardiovascular safety of selective COX-2 inhibitors was directly challenged in August 2001, when independent doctors from the Cleveland Clinic published a meta-analysis of the CLASS trial that concluded these drugs posed an increased risk of adverse cardiovascular events compared to naproxen, a traditional NSAID.

132. Despite the mounting evidence that Bextra caused or exacerbated clot-related cardiovascular disorders, Defendants continued to issue uniformly misleading advertisements and promotional materials touting Bextra as being safe and more effective than traditional NSAIDs for all patients, without regard for gastrointestinal and cardiovascular risks.

133. Defendants' advertising and packaging materials for Bextra are uniformly fraudulent and misleading because they falsely promote Bextra as safe, even though Bextra was known to pose risks of gastrointestinal adverse events, heart attacks, strokes, unstable angina, cardiac clotting, hypertension, and severe skin reactions.

134. At the Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, the Committee concluded that "no clear data shows GI benefit for Celebrex and Bextra." The Committee noted that the GI benefits are "less than first reported," referring to reports by Defendants and others regarding trials they had coordinated purporting to show GI benefits.

E. Defendants' Continued Unlawful Marketing Campaign Caused Overcharges to End-Payors for Bextra

135. As a result of Defendants' claims, Plaintiffs and members of the Class purchased and/or paid for Bextra even though a monthly supply was much more expensive than other NSAIDs.

136. To justify the disparity of Bextra's pricing as compared to other NSAIDs and to ensure that physicians would prescribe and that End-Payors would purchase the drug, Defendants misrepresented the safety and efficacy of Bextra and suppressed the risks, dangers, and disadvantages of the drug. Consequently, Bextra captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of Bextra exceeded $1.2 billion, despite the significantly higher cost of Bextra as compared to other pain relievers in the same family of drugs.

137. Defendants' deceptive and misleading marketing campaign concealed, omitted, and suppressed information that resulted in overcharges to consumers and third-party payors, such as Plaintiffs and the Class, for, in whole or in part, the costs of Bextra. Millions of End-Payors, including consumers and third-party payors, have already paid for, and/or purchased and consumed Bextra at prices based on the proposed wholesale price, which was about one hundred times the cost of a generic aspirin. These End-Payors did not get the benefit of the bargain that Defendants held out to them, and as a result End-Payors paid more than they would have or should have because Bextra was promoted and advertised as a premium drug with reduced side effects for the purpose of deceiving consumers and End-Payors about Bextra's adverse gastrointestinal, cardiovascular, cerebrovascular and cardiorenal effects. Had the truth been told and Bextra not

been promoted contrary to its approved labeling it would not have been placed on formularies and not been paid for by End Payors.

V. FRAUDULENT CONCEALMENT

138. Throughout the Class Period, Defendants affirmatively and fraudulently concealed its unlawful conduct from Plaintiffs and the Class.

139. Plaintiffs and the Class did not discover, and could not discover through the exercise of reasonable diligence, that Defendants were falsely over promoting the safety and efficacy of Bextra until April 7, 2005, when Pfizer withdrew Bextra from the market. Defendants conducted its unlawful activities in secret, concealed the nature of their unlawful conduct, and attempted to confine information concerning the adverse effects of Bextra. Defendants attempted to withhold such information from Plaintiffs and members of the Class, the medical community, regulators and the public. Defendants fraudulently concealed its activities through various means and methods designed to avoid detection.

140. Plaintiffs and the Class could not have discovered Defendants' unlawful conduct at an earlier date through the exercise of reasonable diligence because Defendants actively and purposefully concealed their unlawful activities.

141. Defendants engaged in a successful, illegal fraud on consumers, third-party payors and the general public, by which they deliberately and affirmatively misrepresented the risks, dangers, defects, and disadvantages of Bextra, in at least the following respects:

a. By falsely promoting the safety and efficacy of Bextra to Plaintiffs, the Class, the medical community, and the public in a manner that exceeded the scope of FDA approval;

b. By omitting adverse event risks from its promotions of Bextra to the Class, the medical community, and the public in a manner that made its promotion not fairly balanced and inconsistent with the express label or the intent of the label;

c. By agreements among senior Pfizer and Pharmacia officials in meetings and in communications not to discuss publicly, or otherwise reveal, the totality of the adverse effects

caused by Bextra, Defendants' concealment of those adverse effects, and the nature and substance of other acts and communications in furtherance of Defendants' illegal scheme; and

d. By giving false and pretextual reasons for the existence of apparent adverse effects in studies of COX-2 drugs, including, for example, by claiming that naproxen's cardioprotective effect was responsible for a noted increase in cardiovascular events in the VIGOR study in Vioxx versus naproxen patients, when, in fact, Vioxx is another COX-2 inhibitor which was the cause of the reported increased incidence of cardiovascular effects.

142. As a result of Defendants' fraudulent concealment, Plaintiffs and the Class purchased and/or paid for Bextra and could not reasonably have discovered Defendants' misconduct regarding Bextra prior to April 7, 2005. Plaintiffs and the Class therefore assert the tolling of any applicable statute of limitations affecting the rights of action of Plaintiffs and the Class.

VI. CLASS ACTION ALLEGATIONS

143. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs seek certification of a national Class defined as follows:

> All End-Payors located in the United States, including Consumers and Third-Party Payors,[10] who purchased and/or paid for Bextra.
>
> Excluded from the proposed Class are (i) Defendants, any entity in which Defendants have a controlling interest or which have a controlling interest in Defendant, and Defendants' legal representatives, predecessors, successors and assigns; (ii) the judicial officers to whom this case is assigned; (iii) any member of the immediate families of excluded persons; (iv) governmental agencies and (v) those who resold Bextra.[11]

144. Plaintiffs also define state law subclasses as defined in the various claims for relief in the counts set forth below.

[10] Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

[11] Plaintiffs have named class representatives for the Class, but have not named class representatives for every jurisdiction. Should the Court so require or direct, Plaintiffs are prepared to name proposed class representative Plaintiffs for every jurisdiction, or for each statewide class, and for each subclass the Court may designate.

145. The members of the Class are so numerous that joinder of all their members would be impractical. Bextra has been prescribed to, paid for and ingested by millions of consumers nationwide.

146. There are questions of law and fact common to the Class that predominate over questions affecting only individual members, including, but not limited to:

a. Whether Defendants engaged in a fraudulent and/or deceptive scheme to portray Bextra as a drug having superior qualities to other NSAIDs;

b Whether Defendants engaged in a scheme to create demand for Bextra based on deceptive statements concerning Bextra's safety and efficacy;

c. Whether as a result of this scheme Bextra was over prescribed;

d. Whether unnecessary physician visits were deliberately generated by falsely creating the impression that Bextra – available only by prescription – offered greater benefit than equally effective and far less expensive NSAIDs, several of which could be purchased without a prescription;

e. Whether Defendants are liable to Plaintiffs and the Class for damages under state consumer protection statutes;

f. Whether Defendants made material misrepresentations or material omissions about the cardiovascular and gastrointestinal risks associated with using Bextra and regarding the effectiveness of Bextra; and

g. Whether members of the Class are entitled to damages based on their payments for Bextra, and, if so, the nature and amount of such damages.

147. Plaintiffs' claims and defenses are typical of the claims and defenses belonging to absent members of the Class, because Defendants have uniformly misrepresented that Bextra is safer and more effective than traditional NSAIDs and uniformly omitted skin adverse event risks associated with Bextra. Defendants' actions have deprived Plaintiffs and the members of the Class of their ability to make informed decisions about whether to pay for Bextra and if so at what price.

148. Plaintiffs will fairly and adequately assert and protect the interests of absent members of the Class, because Plaintiffs have retained counsel competent and experienced in complex class action litigation and have no interest adverse to any absent Class Members.

149. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(A), because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class and establish incompatible standards of conduct for Defendants.

150. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(B), because the prosecution of separate actions by individual Class Members would create a risk of adjudications with respects to individual Class Members which would, as a practical matter, be dispositive of the interest of the other members not parties to these adjudications and/or substantially impair their ability to protect these interests.

151. Class certification is proper under Federal Rule of Civil Procedure 23(b)(2), because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate for the Class.

152. Class certification is proper under Federal Rule of Civil Procedure 23(b)(3), because common issues of law and fact predominate over any questions affecting only individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

153. The need for Class-wide notice does not provide a barrier to certification, in that notice can be effectively disseminated to Class by techniques customarily used in consumer class actions, including published notice, Internet notice and direct mailings based on readily available computer databases (such as the one Defendants used to send their “Dear Patient” correspondence).

FIRST CLAIM FOR RELIEF
(Violation of the State Consumer Protection Laws)

154. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

155. Defendants intended that Plaintiffs and Class Members rely on their materially deceptive practices and purchase Bextra as a consequence of the deceptive practices, including Defendants' misrepresentations and omissions of material fact in their marketing of Bextra contrary to its FDA label:

a. Defendants' promotions of Bextra as a safe drug, and as being safer than comparable drugs on the market, were deceptive, unfair, and unlawful in that Bextra actually carried a risk of adverse serious skin reactions, did not have added benefits over older, less expensive NSAIDs, and was promoted solely for financial reasons and not due to any material increase in medical safety or efficacy over NSAIDs;

b. Defendants' conduct was unfair, unlawful, and deceptive in that Defendants knew Bextra was unsafe and increased the risk of adverse cardiovascular events, such as heart attack and stroke, to unacceptable levels, but falsely promoted the cardiovascular safety to doctors, third party payors and patients until 2005;

c. Defendants' conduct was unfair, unlawful and deceptive in that Defendants' falsely advertised that scientific studies showed a clinical benefit over other NSAIDs that would offset any risk of serious skin reactions (*e.g.*, toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme), such as studies that purported to show superior GI safety, general safety and/or superior efficacy, such studies were misleading both in their design and their use as promotional materials for Bextra.

d. Defendants' conduct was unfair, unlawful, and deceptive in that they falsely represented that Bextra was proven safe in clinical trials even though trials had been conducted comparing Bextra to placebos and non-selective NSAIDs that contradicted that claim including the two short term trials of patients provided Bextra after coronary artery bypass graft ("CABG") surgery that had a two-fold increases in the risk of serious adverse cardiovascular events compared to placebos.

e. Blitzing doctors' offices with literature falsely claiming that Bextra was superior to NSAIDs with respect to GI side effects and with material that did not fairly balance the CV risks of Bextra;

f. Instructing sales agents to hide CV risks and/or the lack of approval for pain relief and in fact claiming "pain" superiority when pitching Bextra, contrary to its approved labeling;

g. Issuing advertisements that lacked a fair balance concerning the safety and efficacy of Bextra;

h. Defendants' conduct was unfair, unlawful, and deceptive in that they falsely claimed that Bextra was superior to other NSAIDs in the vast majority of patients;

i. Defendants portrayed Bextra as a relief for symptoms and diseases without any statistically significant evidence for doing so;

j. Defendants falsely portrayed Bextra with knowledge of such falsity in order to induce doctors to prescribe Bextra and consumers to purchase Bextra at a price that exceeded its actual worth;

k. Defendants established Bextra as a standard course of treatment based upon the purchase and distribution of reprints of articles appearing in prestigious medical journals which Defendants knew were false and/or misleading; and

l. Defendants committed unlawful acts by promoting and advertising Bextra in a manner that violated the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f), and (n) and 355(a).

156. Defendants' deceptive representations and material omissions to Plaintiffs and the Class Members were, and are, unfair and deceptive acts and practices.

157. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes that allow third-party payors to bring claims. Plaintiffs assert this claim on behalf of third-party payors who are Class Members located in the states that permit TPP claims under the consumer protection laws as set forth below.

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code §§ 4-88-101, *et seq.*, including § 4-88-113(f), and § 4-8-102(5);

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and the Consumer Legal Remedies Act ("CLRA") § 1750, *et seq.* and §§ 1770(e) and (g) of the Civ. Code;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*, including § 6-1-113(1)(c) and § 6-1-102(b);

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*, including § 42-110(a)(3);

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*, including 6 Del. Code § 2512;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*, including § 28-390(1);

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*, including § 481A-2;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*, including § 48-602;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq., including § 13-101(h);

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, including § 445-902(c);

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*, including § 407.010(5);

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*, including § 30-14-102(5);

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, including § 59-160(1);

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*, including § 358-A:1(1);

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*, § 56:8-1(d);

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*, including § 51-15-01(4);

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*, including § 646.605(4);

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*, including § 201-2(2);

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*, including § 6-13.1(3);

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*, including § 39-5-10(9);

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, including § 37-24-1(8);

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, including § 47-18-103(9);

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*, including § 59.1-198;

(ll) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, including § 19.86.010(1);

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*; and

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*, including § 40-12-102(a)(i).

158. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes that allow consumers to pursue claims. Plaintiffs thus assert this claim on behalf of Class Members in the states identified below and pursuant to the statutes identified below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and the Consumer Legal Remedies Act, Civ. Code § 1750 *et seq.*; and §§ 1770(e) and (g);

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

(qq) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

(rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(ss) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*; and

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

159. Plaintiffs provided notice of this litigation as follows: On March 1, 2006, notice was sent to each Attorney General in each of the states requiring notice and where demand on a defendant is required, such demand was made on March 1, 2006.

160. Pursuant to Section 1782 of the CLRA, in conjunction with the filing of this action, Plaintiffs have notified Defendants in writing of the particular violations of Section 1770 of the CLRA (the "Notice") and has demanded that Defendants refund the purchase price of Bextra. Plaintiffs sent the Notice by certified mail, return-receipt requested to Defendants' registered agent of service/principal place of business in California.

161. If Defendants deny the existence of the defect in Bextra and notify Plaintiffs' Counsel that they will not comply with the demand that Plaintiffs included in Notice, Plaintiffs will amend to request actual damages under Section 1750 on behalf of themselves and all other persons and entities who have purchased and/or paid for Bextra.

162. If Plaintiffs and members of the Class had not been deceived concerning the safety and effectiveness of Bextra, they would have taken steps so as to not purchase Bextra at the prices

set by Defendants, or would not have purchased Bextra, or would not have paid for physician visits to obtain prescriptions for Bextra, which offered no meaningful advantage and posed greater risk of harm than equally effective and far less expensive NSAIDs, available without a prescription. Among the possible steps taken would be to exclude Bextra from approved formulary schedules, set a lower scheduled value in the formulary, set a high co-pay obligation, and otherwise dissuade doctors from prescribing Bextra, or to not purchase Bextra.

163. Defendants' unlawful actions caused the purchase of, or payment for Bextra by Plaintiffs and payment for physician visits to discuss or obtain prescriptions for Bextra and as a result Plaintiffs paid more than they otherwise would have for NSAIDs: had a reasonable plaintiff known the truth that Defendants misrepresented and concealed that Plaintiffs would have used and/or paid for another, cheaper NSAIDs or would have purchased nothing and lived with the pain, Defendants would have lost a sale, and Plaintiffs would have avoided a loss.

164. Plaintiffs and members of the Class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at physicians and consumers was to artificially create demand for Bextra in lieu of other NSAIDs and/or caused Bextra to command overpayments from Plaintiffs and Class Members. Each aspect of Defendants' conduct combined to artificially create sales of Bextra.

165. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and the Class have suffered actual economic damage by paying for Bextra and unnecessary physician visits related thereto in lieu of other less expensive, equally effective and safer drugs and/or to pay at an artificially inflated price.

166. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, significant sums of money from Plaintiffs and the Class Members.

167. As a proximate result of the Defendants' misrepresentations, Plaintiffs and the Class Members have suffered ascertainable losses in an amount to be determined at trial.

SECOND CLAIM FOR RELIEF
(Unjust Enrichment)

168. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

169. To the detriment of Plaintiffs and members of the Class, Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, *inter alia*, payments for Bextra.

170. Defendants have unjustly benefited through the unlawful and/or wrongful collection of, *inter alia*, payments for Bextra and continue to so benefit to the detriment and at the expense of Plaintiffs and members of the Class.

171. Accordingly, Plaintiffs and members of the Class seek full restitution of Defendants' enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable, and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring Plaintiffs as representatives of the Class and Plaintiffs' counsel as counsel for the Class; and designating such 23(c)(4)(A) class issues and/or 23 (c)(4)(B) subclasses as it may deem appropriate.

B. The conduct alleged herein be declared, adjudged, and decreed to be unlawful;

C. Plaintiffs and the Class be granted an award of damages in such amount to be determined at trial, with treble damages as provided by law;

D. Plaintiffs and the Class be granted an award of punitive damages in such amount to be determined at trial;

E. Defendants be enjoined from continuing the illegal activities alleged herein;

F. Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

G. Plaintiffs and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

VIII. DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

DATED: January 5, 2007

Respectfully submitted,

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